Nicomedes Sy Herrera (State Bar No. 275332)
Andrew Purdy (State Bar No. 261912)
Laura E. Seidl (State Bar No. 269891)
HERRERA PURDY LLP
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
Facsimile: (855) 969-2050
Email: NHerrera@HerreraPurdy.com
APurdy@HerreraPurdy.com
LSeidl@HerreraPurdy.com

Tejinder Singh (*Pro Hac Vice*)
GOLDSTEIN & RUSSELL, P.C.
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
Email: TSingh@GoldsteinRussell.com

Attorneys for Plaintiff-Relator Zachary Silbersher

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

Case No.: 3:18-cv-03018-JCS

PLAINTIFF-RELATOR ZACHARY SILBERSHER'S OPPOSITION TO ALLERGAN DEFENDANTS' MOTION TO DISMISS (DKT. 63)

Hon. Joseph C. Spero

Courtroom G, 15th Floor
Phillip Burton Federal Building
450 Golden Gate Avenue
San Francisco, CA 94102

Hearing Date: October 25, 2019
at 9:30 a.m. (Dkt. 76)

Action Filed: April 25, 2018

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INTRODUCTION

The First Amended Complaint (Dkt. 12) ("Complaint") alleges that Defendants[1] committed fraud to cause the United States and Plaintiff States to pay substantially more for the drugs Namenda XR (memantine) and Namzaric (memantine and donepezil) than they would have otherwise paid. Specifically, Defendants misled the Patent Office into issuing invalid patents protecting these drugs. They then submitted the invalid patents to be listed in the FDA's database of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." (Complaint, ¶¶ 1, 141) Defendants were permitted to submit for listing only valid patents that "could reasonably be asserted" against generic competitors. *See* 21 U.S.C. § 355(b)(1). Defendants, however, knowingly submitted the fraudulent patents to the government for listing in the Orange Book to block generic competitors' entry into the market through drawn-out compulsory patent litigation resulting from the Orange Book listings.

Generic competition would have decreased Defendants' market share by as much as 90% and brought market prices down by as much as 90%. (*Id.*, ¶¶ 47, 122, 126, 155(f), (g), 157) Defendants used the resulting inflated prices to obtain inflated reimbursement rates with the government and charge inflated prices to government agencies directly purchasing the drugs. Defendants also reported those prices to the government as if they were fair and reasonable when Defendants knew they were unlawfully inflated through their fraudulent scheme. Defendants' "fraudulent course of conduct" caused government programs to pay too much for the drugs, violating the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. *See U.S.* ex rel. *Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). The total damages to the government likely exceeded $2 billion.

Using fraud or a fraudulent scheme to cause the government to pay too much for goods is a heartland violation of the FCA. For example, if a defendant reported inaccurate market prices to the government during pricing negotiations to inflate the price the government would pay, the FCA would impose liability for the subsequent claims. The fact that Defendants here manipulated the market price

[1] Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. (collectively, "Allergan"); and Adamas Pharma and Adamas Pharmaceuticals, Inc. (together, "Adamas") ("Allergan" and "Adamas" together, "Defendants").

through an upstream fraud—instead of merely misreporting it—does not make their conduct less culpable, or the statute less applicable. Indeed, it is well-settled that when a defendant commits an upstream fraud that taints downstream claims for reimbursement, the claims are actionable even if they are not, on their face, false. *See Campie*, 862 F.3d 890; *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006). Here, the Complaint alleges that the point of Defendants' fraud was to maintain an unlawful monopoly, resulting in higher prices for all payors, including the government. The harm to the government fisc was not some fortuitous byproduct of a garden-variety regulatory violation. It was the *raison d'etre* of a deliberate fraud.

Allergan's arguments do not seriously attack this theory of fraud head-on. Instead, Allergan unpersuasively picks around the edges of the Complaint. Allergan's arguments about U.S. Patent No. 8,039,009 ("the '009 Patent") misconstrue the applicable legal standard, mischaracterize the Complaint, and would not justify dismissal even if they were correct. Allergan's protest that it did not participate in the fraud relating to the Went Patents ignore the fact that Allergan's predecessor in interest, Forest Laboratories, Inc. ("Forest"), engaged in fraudulent conduct after obtaining an exclusive license for the patents. Allergan's assertion that Defendants' claims were not false ignores settled law holding that upstream frauds taint downstream claims, and disregards that the government relies on market prices to reflect fair conditions. Allergan's perfunctory materiality argument is implausible in light of the magnitude of Defendants' fraud and the government's documented concern with inflated brand-name drug prices.

Instead of defending its conduct, Allergan spend most of its motion discussing the FCA's "public disclosure" provision, 31 U.S.C. § 3730(e)(4)—which has nothing to do with whether Defendants committed fraud. It is a classic move for Defendants that have bilked the healthcare system to disparage the whistleblower challenging their fraud as an opportunistic "parasite."[2] But Allergan's public disclosure arguments miss the mark.

[2] "Parasitic" suits barred by the FCA are typified by cases where individuals merely copy allegations of fraud of existing government investigations to receive a cut. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 63 (1943); H.R. Rep. 102-837 (1992). That is not the case here. Mr. Silbersher did not bring this suit to parasitically grab a portion of the government's recovery from an already existing lawsuit or investigation. To the contrary, if Relator had not filed this action, it is clear the government

Principally, Allergan argues that the Complaint should be dismissed because some of the underlying facts can be found in patent prosecution dockets. That is unpersuasive for a litany of reasons, the most obvious of which is that it would thwart Congress's decision in 2010 to limit the civil, criminal, or administrative hearings or proceedings that would trigger the public disclosure bar only to those in which "the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i). The addition of that language excludes patent prosecutions, which are *ex parte* administrative proceedings in which the government is not a party. Allergan's argument would render this exclusion a nullity, in conflict with the statutory text, controlling precedent, and Congress's policy objectives in narrowing the public disclosure bar and strengthening the FCA.

Moreover, there is nothing "parasitic" about this action. The high cost of prescription drugs is one of the most intractable problems facing the American healthcare system, and patent monopolies are a significant driver of drug costs. When, as here, drug manufacturers breach their duty of candor and good faith to the Patent Office and prolong their patent monopolies by fraud, patients and the government both suffer greatly. It takes a great deal of expertise and investigation to identify and analyze pharmaceutical patents that are *not just invalid*, but also obtained through *fraud*. Identifying such fraud is not reasonably ascertainable by government prosecutors, and they must rely on those with specialized knowledge to bring suit. Mr. Silbersher is the only person who has done that work to recover the billions that Defendants overcharged the government for Namenda XR and Namzaric. Thus, even if there had been "public disclosure" of all the material elements of fraud alleged in the Complaint in the specific public *fora* enumerated in the statute—and there has not been—Relator may nevertheless proceed because the FCA, as amended by Congress in 2010, recognizes that Mr. Silbersher is an "original source" of information that "materially adds to" any publicly-available ones.

The Motion to Dismiss should therefore be denied.

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would never have even known of the fraud or recovered the billions that Defendants have overcharged the government. Defendants correctly say there are "parasites" here—but Relator is not one of them.

BACKGROUND

Allergan manufactures, sells, and distributes Namenda XR and Namzaric in partnership with Adamas (Complaint, ¶¶ 49, 53). Both drugs are used to treat dementia related to Alzheimer's disease. These drugs are expensive and make serious money for Defendants. For example, the Complaint alleges that in 2014 and 2015 alone, Medicare reimbursed approximately 5.4 million prescriptions for Namenda XR for approximately $1.46 billion. (Complaint, ¶ 132).

The Complaint alleges that Defendants obtained the patents protecting Namenda XR and Namzaric by fraud. The first set of patents, known as the Went Patents, were only granted because Dr. Gregory Went, the CEO of Defendant Adamas, misrepresented the results of a clinical study (the ME110 Study), asserting that the study showed a low incidence of certain side effects, when in fact the opposite was true. (Complaint, ¶¶ 66-69, 73) Went and Adamas continued to resubmit the same fraudulent data, and never corrected their misrepresentation, when applying for nine additional patents, each time misleading the Patent Office into granting the applications. (*Id.*, ¶¶ 73-90). Two of those applications, for U.S. Patent Nos. 8,580,858 and 8,598,233, were filed on December 21, 2012, and January 28, 2013, after Allergan's predecessor in interest, Forest, had entered into an exclusive licensing agreement with Adamas to commercialize the Went Patents. The Went Patents were subsequently found to be invalid; those findings were affirmed on appeal; and generic competition began immediately thereafter. (*Id.*, ¶ 51, 107).

The second relevant patent, the '009 Patent, was obtained directly by Forest—again by misleading the Patent Office. The application for the '009 Patent had been rejected at least six times when, on March 15, 2011, Forest amended it to require "once daily administration" of the drug. (Complaint, ¶ 96) Forest claimed that this was a novel feature—but in fact it was invalid as obvious in view of U.S. Patent No. 6,479,553 ("the '553 Patent"), which expressly teaches treating Alzheimer's disease by administering memantine once daily. (Complaint, ¶ 93). The '553 Patent had been mentioned to the patent Examiner in 2009 (eighteen months beforehand), but Forest misleadingly omitted any reference to it after changing its application to require once-daily administration. The Complaint alleges that this omission was intentional—which is plausible because Forest's prior

citation to the '553 Patent demonstrated that Forest knew of that patent and understood its claims. Had Forest candidly disclosed the '553 Patent after it amended its application, the '009 Patent would not have issued. (*Id*., ¶ 97) Unless invalidated, the '009 Patent will protect Namzaric until 2029.

The Complaint alleges these patents were obtained in violation of Defendants' affirmative duty of candor and good faith to the Patent Office. That duty is embodied in a federal regulation, which provides that:

> A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a **duty of candor and good faith** in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. **The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned**. . . . There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. **However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct**.

37 C.F.R. § 1.56 (emphasis added). Because patent prosecution is an *ex parte* proceeding, the Patent Office relies on parties prosecuting a patent—including all real parties-in-interest—to provide patent Examiners with all material information necessary to fairly determine patentability, particularly if such information would have a tendency to refute patentability. *See* Manual of Patent Examining Procedure, § 2001.04*; see also* Complaint ¶¶ 46, 99. And as the text of the rule establishes, an applicant violates this duty *per se* by engaging in actual or attempted fraud, or bad faith or intentional misconduct.

After obtaining these patents, Defendants listed them in the FDA's Orange Book. (Complaint, ¶¶ 1, 141) This is significant because a generic manufacturer seeking FDA approval of an Abbreviated New Drug Application ("ANDA") must certify that the generic drug will not infringe a patent listed in the Orange Book. If the brand drug is covered by a patent that has not yet expired, then a generic manufacturer must submit a so-called Paragraph IV certification, which states that the listed patent is

invalid or will not be infringed. (*Id*., ¶ 40) When a generic manufacturer files a Paragraph IV certification, the brand-name manufacturer can immediately sue the generic manufacturer for infringement—and by statute, the initiation of such litigation delays approval of the ANDA for at least 30 months. (*Id*., ¶ 43)

The Complaint alleges that Defendants used their fraudulently obtained patents to substantially delay generic competition for Namenda XR and Namzaric. It alleges that sixteen generic manufacturers had filed ANDAs and were prepared to enter the market for Namenda XR at the end of December 2013, but Defendants delayed that entry by listing their patents in the Orange Book and initiating infringement actions asserting six of the Went Patents against all the ANDA filers, and the '009 Patent against nine of the ANDA filers. As a result, no generic manufacturers entered the market for Namenda XR until February 2018. (Complaint, ¶¶ 107-08) The Complaint further alleges that Defendants asserted the Went Patents against all the ANDA filers for Namzaric, and asserted the '009 Patent against all but one of those filers—and that but for the assertion of these fraudulently obtained patents, generic competition could have begun as early as July 13, 2015. (*Id*., ¶¶ 108-09)

Delaying or blocking generic competition has been very valuable for Defendants. After the onset of generic competition for Namenda IR (the instant release counterpart to Namenda XR's extended release formulation), Allergan's revenues for Namenda IR dropped approximately 97.3%, year over year. (Complaint, ¶ 133) Given the number of generic manufacturers interested in offering alternatives to Namenda XR and Namzaric, the Complaint plausibly alleges the prices of these drugs would have declined by at least 90%. But because of Defendants' fraud, Defendants maintained their monopoly prices and market share.

This fraud harmed the government in two ways. First, government health care programs frequently favor less expensive generic drugs. By unlawfully excluding generic competitors from the market altogether, Defendants denied these government programs that choice, and therefore deprived the government of significant cost savings.

Second, the prices the government pays for drugs are based on market prices. Thus, when a drug manufacturer unlawfully manipulates the market price, it necessarily also manipulates the price

the government will pay. For many programs, including Medicaid and direct purchases by the government, manufacturers must report their best prices to the General Services Administration ("GSA") so that the GSA can determine the price for the Federal Supply Schedule ("FSS"). Manufacturers are required to regularly update the prices they charge to commercial payors, and those prices are used to calculate the maximum price that a vendor can charge, or the government may pay, for a drug under many government programs.[3] (Complaint, ¶ 112) The GSA's objective, for which it requires proof from the manufacturers, is to determine a "fair and reasonable" price for the government (Complaint, ¶ 112-14) Other programs, including Medicare Part D, use similar mechanisms to determine their pricing: they rely on the market price to help determine a fair price for the government. Thus, when a manufacturer fraudulently manipulates the market price for a drug, that fraud imposes significant costs on the government.

This case is a perfect illustration. According to the most recent data published by the Centers for Medicare and Medicaid Services ("CMS"), Medicare Part D and Medicaid paid a total of $3.122 billion from July 2014 to December 31, 2017 (the last date data is available) for Namenda XR and Namzaric based on over 8.5 million separate claims.[4] These amounts do not include direct government purchases, such as through the Veterans' Health Administration or the Department of Defense's TRICARE. The government would have paid a lot less for these drugs—90% less—if generic alternatives had been available.

ARGUMENT

As the Ninth Circuit has repeatedly held, the FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Hendow*, 461 F.3d at 1170–71; *see also Campie*, 862 F.3d at 899 ("We construe the Act broadly"). To allege an FCA claim,

[3] By inflating the market prices, Defendants also inflated the Federal Ceiling Price for most government agencies directly purchasing drugs, as well as the "Best Price" for Medicaid reimbursement for single-source drugs. Those prices establish the maximum price that a vendor can charge the government at a percentage (approximately 76%) of the Average Manufacturer Price for the drugs.

[4] The data through 2017 was unavailable when the First Amended Complaint was filed but can now be accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.

Relator must plead: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Campie*, 862 F.3d at 899. The Complaint satisfies each and every element of an FCA claim. As explained in the Introduction, and as established by the allegations in the Complaint and the foregoing summary, this case falls squarely within the heartland of the FCA: Defendants used fraud to cause the government to pay more for medicines.

To be clear, the Complaint alleges that Defendants did three fraudulent things, each of which tainted claims for payment made to the government: (1) Defendants obtained their patents through fraud on the Patent Office; (2) Defendants knowingly used these fraudulent patents to block or delay generic competition, inflating the market price and securing their market share through fraud (and thus denying government payors choice in the marketplace); and (3) Defendants provided tainted and misleading pricing information to government payors, leading to contracts that caused the government to pay Defendants more than it otherwise would have. These actions sound in promissory fraud, a well-recognized theory of liability under the FCA. *See, e.g.*, *Campie*, 862 F.3d at 902 (explaining that under this theory, "subsequent claims are false because of an *original fraud* (whether a certification or otherwise)") (quotation marks omitted).

Because Defendants also provided tainted and misleading price information that Defendants represented to have been "fair and reasonable," Defendants are also liable under an implied certification theory because a government purchaser would have reasonably, but incorrectly, understood that Defendants' pricing information reflected fair market conditions and were not inflated through the wrongful exclusion of competitors. *See Escobar*, 136 S. Ct. at 2000-01; *Campie*, 862 F.3d at 901.

Taking the allegations in the Complaint as true, none of Allergan's contentions justify dismissing this case at the pleading stage.

I. Allergan Misled the Patent Office Into Issuing the '009 Patent

The Complaint alleges that Allergan's predecessor in interest, Forest, obtained the '009 Patent by fraud. (Complaint, ¶¶ 16, 91-102) The assertedly novel feature of the patent (*i.e.*, once-daily

administration of the drug) was already taught by the '553 Patent, which Forest never mentioned to the Examiner after amending its application to claim for the first time that very feature. Allergan argues (MTD, at 19-21) that Forest did not mislead the Patent Office because it had disclosed the '553 Patent to the Examiner approximately eighteen months earlier—before the application was amended to claim daily administration (thus, at a time when that claim in the '553 Patent was not relevant to patentability on this basis). Allergan's argument is unpersuasive.

At the outset, even if Allergan's argument were correct, it would not justify dismissal of the Complaint for two reasons. First, the '009 Patent was not asserted against all of the generic manufacturers—which means that at least some of them could have entered the market even if the '009 Patent had not been obtained by fraud. (Complaint ¶¶ 101, 107-08) (showing which patents were asserted against which generic manufacturers) The fraud relating to the '009 Patent thus relates to the proper measure of damages (because more generic entrants mean a greater price drop and less market share for Defendants)—not to deciding whether the Complaint should be dismissed *en toto*.

Second, even if Forest did not initially obtain the '009 Patent by fraud, the patent nevertheless is plainly invalid as obvious over the '553 Patent. Allergan thus knowingly or recklessly asserted the invalid patent to block generic competitors from the market so that it could charge the government monopoly prices and remove the government's ability to purchase less expensive generics. Such misconduct is independently culpable under the FCA.

Allergan relies on the wrong legal standard in citing cases based on the affirmative defense of "inequitable conduct." Inequitable conduct is an affirmative defense to patent infringement, and it has been described as "the 'atomic bomb' of patent law" because it "render[s] the entire patent," as opposed to individual claims, "unenforceable"; it "cannot be cured by reissue, or reexamination"; and it can "spread from a single patent to render unenforceable other related patents and applications in the same technology family," endangering "a substantial portion of a company's patent portfolio." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (citation omitted). These and other concerns led the Federal Circuit in *Therasense* to "tighten[] the standards for finding both intent and materiality" in inequitable conduct defenses. *Id*. at 1290.

In contrast, the FCA has its own, statutory standards for intent and materiality, which are looser than the standards for inequitable conduct. The Supreme Court has made clear that FCA claims need only satisfy common law elements for fraud. *Universal Health Servs., Inc. v. U.S.* ex rel. *Escobar*, 136 S. Ct. 1989, 1999 (2016). The FCA's intent standard can be satisfied by intentional conduct or by recklessness and requires "no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). The FCA's standard for materiality means "having a natural tendency to influence, or be capable of influencing, the receipt of money or property." *Id.* § 3729(b)(4). As the Supreme Court has explained, under this standard, a matter is material if a reasonable person would attach importance to it, or if the defendant knew or had reason to know that the government would attach importance to it, even if a reasonable person would not. *See Escobar*, 136 S. Ct. at 2002-03. Moreover, it is well-established that a misleading omission is actionable as fraud. *See id.* at 1999.

Because FCA liability is broader than the inequitable conduct standard, it follows that every act of inequitable conduct (such as a violation of the duty of candor and good faith) would also satisfy the FCA's materiality and intent requirements—but the converse is not necessarily true. Thus, even if the prior disclosure of the '553 Patent might save the '009 Patent from a charge of inequitable conduct, it would not follow as a matter of law that such a disclosure also vitiates FCA liability. Instead, the question would be whether misleading omissions to the Patent Office constituted fraud under the FCA's test, *i.e.*, if they were misleading, made at least recklessly, and related to information that would have been important to a reasonable patent Examiner. Here, the Complaint survives a motion to dismiss because it alleges that the omission of the '553 Patent after the amendment of the '009 application was misleading, and that the claims of the '553 Patent would have been important to a reasonable Examiner. (Complaint, ¶¶ 91-102) Whether the omission was intentional or merely reckless, it violated the FCA.

Even considering the matter through the lens of inequitable conduct, Allergan's argument is wrong. The Complaint alleges that Forest *intentionally* omitted the disclosure of the '553 Patent after amending the application *because* it knew that the disclosure would scuttle its application. (Complaint, ¶¶ 94, 97) Under 37 C.F.R. § 1.56, "intentional misconduct" is a bar to patentability. At the pleading

stage, Allergan's claim that Forest did not act intentionally cannot be credited because the allegation is at least plausible in light of Forest's knowledge of what the '553 Patent claimed, and these sort of scienter questions are typically matters for a trier of fact, even in inequitable conduct cases (and certainly in FCA cases). *See, e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 90 F.Supp.2d 522, 528 (D.N.J. 2000) ("[A] fact finder may infer deceptive intent when a patent applicant withholds potentially pertinent information and makes arguments for patentability which could not have been made had the information been disclosed."); *Skedco, Inc. v. Strategic Operations, Inc.*, 287 F.Supp.3d 1100, 1149–1150 (D. Or. 2018) (denying summary judgment against inequitable conduct claim even though three patents had previously been disclosed to the PTO in the same application). Allergan also is wrong to argue that the allegations about Forest's intent fail to satisfy Rule 9(b), because the text of the Rule expressly provides that knowledge can be pleaded "generally." Fed. R. Civ. P. 9(b). *See also U.S.* ex rel. *Integra Med Analytics LLC v. Providence Health & Servs.*, No. CV 17-1694 PSG (SSX), 2019 WL 3282619, at *22 (C.D. Cal. July 16, 2019) (holding that the complaint sufficiently alleged Defendants were seeking to increase Medicare revenue and were reckless).

More broadly, context matters in determining whether an applicant satisfied its duty of candor and good faith. The disclosure of the '553 Patent eighteen months prior to the amendment of the application for the '009 Patent, for a purpose that had nothing to do with its later relevance, certainly did not satisfy Forest's duty to the Patent Office *as a matter of law*.[5] Rule 1.56(a) requires that "at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability." 37 C.F.R. § 1.56. Omitting prior art during the course of amending a patent application violates the letter of Rule 1.56(a) because it results in the failure to disclose material information during the "time an application is being examined." If anything, Forest's disclosure of the '553 Patent eighteen months before it became relevant was likely to mislead. The Examiner would have considered that patent and determined that it was not relevant to patentability.

[5] To rule that Forest satisfied its duty as a matter of law would invite mischief and fraud: Patent applicants would be incentivized to initially list numerous, largely irrelevant prior art citations knowing that they could amend the application later to add claims that would make the prior art citations buried in old filings extremely relevant, but effectively hidden from the Examiner.

The Examiner would not likely have revisited it without prompting when, more than a year later, Forest amended its application and fundamentally changed that calculus. (Complaint, ¶ 96).[6]

Allergan's authorities regarding cumulative disclosures concern different facts. *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000), concerned an alleged failure to emphasize prior art references that the Examiner specifically considered and crossed-out; there was no change in the scope of what was being claimed that altered the relevance of the prior art. In *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1185 (Fed. Cir. 1995), the prior art reference was "already of record" because it was in the application from which the Patent Office based the patent. In *Pixion, Inc. v. Citrix Sys., Inc.*, 2012 WL 1309170 (N.D. Cal. Apr. 16, 2012) the prior art references in "child" applications were cumulative because the patents were all granted based on a similar theory. *Id.* at *4 ("The child patents are derivative of the parent patents."). Here, by contrast, when it was disclosed in 2009, the pending claims did not yet require once-daily administration, and thus, the Examiner had no reason to cite to the '553 Patent as prior art for this limitation. The '553 Patent became critically relevant later, but at that point, Forest omitted any mention of it.

Allergan's scienter argument that Forest relied on an "objectively reasonable" interpretation of 37 C.F.R. § 1.56 in determining that the '553 Patent need not be disclosed in the amended application for the '009 Patent (MTD, at 20-21) is an attempt to dispute Relator's well-pleaded facts. Relator alleges that Forest failed to disclose the '553 Patent because it knew disclosure of the "very limitation" it sought to patent would make once-daily administration obvious and "the '009 Patent would not have been allowed." (Complaint, ¶¶ 96-97) Forest's failure to disclose was not due to some type of mistake about what sort of disclosure was required—Forest acted with intent to conceal the teachings of the '553 Patent.[7] Whether Forest's failure to disclose was strategic, reckless, or based on a good-faith misapprehension of what 37 C.F.R. § 1.56 requires cannot be resolved on the pleadings.

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[6] The prosecution docket for the '009 Patent includes a statement by the Examiner, dated September 28, 2009, and filed on October 7, 2009, confirming that the '553 patent was considered as of that date.

[7] Allergan's authorities concerning FCA liability in circumstances under which defendants believed their conduct was lawful or otherwise proper have no application here, because Relator alleges exactly the opposite. *United States ex rel. Haight v. Catholic Healthcare W.*, 2007 WL 2330790, at *6 (D. Ariz. Aug. 14, 2007) (study grant did not require defendant to provide dogs for study); *United States ex rel. McGrath v. Microsemi Corporation*, 690 Fed. Appx. 551, 552 (9th Cir. 2017) (no allegations

Independently, for the reasons explained above, Allergan's suggestion that 37 C.F.R. § 1.56 would reasonably permit an applicant to hide the ball in the way Forest did is not "objectively reasonable." It is self-serving and utterly contrary to the letter and spirit of the rule.

II. Allergan Participated in the Fraud Relating to the Went Patents

Allergan does not dispute that the Went Patents were obtained by fraud because Dr. Went lied about the results of the ME110 Study, and his lies caused the Patent Office to issue the Went Patents. Instead, Allergan argues (MTD, at 21-25) that the Went Patents were prosecuted by Dr. Went and Adamas, and not by Forest, such that Allergan, as the successor in interest to Forest, is not liable for fraud in connection with those patents.

First, Allergan ignores that the fraud in the Complaint is not limited to obtaining the patents. The fraudulent scheme also encompasses asserting the patents against generic competitors to unlawfully inflate the prices that the government paid for the drugs, and also to take away the government's ability to choose less-expensive generics that would be sold by Defendants' competitors. Forest and Allergan were involved in all of that subsequent fraudulent conduct, and therefore are jointly and severally liable even if they were not present when the Patent Office was first defrauded. *See, e.g., Mortgs., Inc. v. United States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991); *United States v. Bourseau*, No. 03-CV-907-BEN(WMC), 2006 WL 2961105, at *13 (S.D. Cal. Sept. 29, 2006).

Analogizing to inequitable conduct cases (from which this case is *a fortiori*), Allergan would be liable even if Forest had no role in the fraud because, in cases involving allegations of inequitable conduct, the consequences of patent fraud do not disappear when a patent is transferred to an innocent third-party. Instead, the Federal Circuit has confirmed that a patent-plaintiff is liable for asserting patents acquired from a third party that committed inequitable conduct—even though there was no

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defendant knowingly violated arms trafficking statute); *United States ex rel. Donegan v. Anesthesia Assn's. of Kan. City*, 833 F.3d 874, 879 (8th Cir. 2016) (ambiguity in term "emergence" prevented knowing wrongdoing). *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) is inapposite for this reason, and also because the underlying statute used "imprecise and discretionary language" to define what allocation of costs were allowed, whereas Rule 1.56 uses an objective "reasonable examiner" standard.

direct evidence that the plaintiff previously knew about the misconduct—because the plaintiff "should have known" that the patents "were unenforceable." *See In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1272 (Fed. Cir. 2018).

Second, Allergan's chronology is contrary to the allegations in the Complaint. As Allergan acknowledges, Forest executed an exclusive licensing agreement with Adamas in November 2012. Applications for two of the Went Patents—U.S. Patent Nos. 8,580,858 and 8,598,233—were filed after that date, on December 21, 2012 and January 28, 2013, respectively. In connection with those applications, the same misleading statements about the ME110 Study were submitted to the PTO. At a minimum, Forest was complicit in that fraud because, as the exclusive licensee, it was a real-party-in-interest for the patents at that time, and it had a duty of candor and good faith to the Patent Office that it did not honor. 37 C.F.R. § 1.56(c)(3) (pre-AIA) (duty of candor applies to "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application").

Finally, Allergan argues that the Complaint does not allege that either Forest or Allergan knew of the fraud on the Patent Office. But as just noted, Forest was already the exclusive licensee when two fraudulent patent applications were submitted, and it was at least reckless with respect to the information submitted in those applications. Moreover, Dr. Went's fraud, which Allergan does not dispute, is chargeable to all those who acquire or enforce the patents. *See Rembrandt*, 899 F.3d at 1272; *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("If an individual who is substantively involved in the preparation or prosecution of an application fails to comply with his duty of candor, then that individual's misconduct is chargeable to the applicant for the patent, and the applicant's patent is held unenforceable."). Put another way: Fraud on the Patent Office cannot be laundered out by transferring the interest in the fraudulently obtained patents to a third party.

In sum, Allergan is not entitled to dismissal. As the successor in interest to Forest, which was the exclusive licensee of the Went Patents, Allergan is liable for how these patents were obtained, and then used to exploit the government.

III. The Complaint Pleads False Claims and Statements

Allergan argues (MTD, at 25-28) that the Complaint does not allege that it or Forest made any false claims or statements. The FCA is broadly construed to apply to claims that are "false or fraudulent," 31 U.S.C. § 3729(a)(1)(A), (B), and not only to claims that are literally false. This includes misleading omissions, *Escobar*, 136 S. Ct. 1989; and it includes situations in which an upstream fraud is used to facilitate downstream claims, *Campie*, 862 F.3d at 903 and *Hendow*, 461 F.3d at 1174. *See also U.S.* ex rel. *Marcus v. Hess*, 317 U.S. 537, 539 & n.1, 542-44 (1943) (explaining that after a group of contractors had used rigged bidding to obtain various contracts, the "fraud did not spend itself with the execution of the contract," because its "taint entered into every swollen estimate which was the basic cause for payment" downstream).

Defendants' upstream misrepresentations and omissions to the Patent Office were fraudulent, and they render the subsequent downstream claims for reimbursement actionable. In *Campie*, the Ninth Circuit reversed the dismissal of an FCA complaint alleging that Gilead obtained FDA approval of its drugs through false statements to the FDA. Foreign manufacturing locations must register with the FDA before drugs made in those locations can be imported into the U.S. The *Campie* relators alleged that Gilead manufactured its drugs in unregistered locations, which relators claimed made them ineligible for payment, rendering all downstream claims for payment false or fraudulent under the FCA. *Id.*, 862 F.3d at 896. The Ninth Circuit held that those allegations support FCA liability.

Relator's claims here present an even stronger case under the FCA than those in *Campie*. In *Campie*, there was no allegation that the invoices for Gilead's drugs mentioned *anything* concerning the location where the drugs were manufactured. The court did not even require proof that the drugs were worthless or unusable, or that the government paid too much compared with the drug's intrinsic economic value. *Id.* at 900. Here, the claims for payment specifically included prices that had been unlawfully manipulated by Defendants, and the government was actually overcharged by 1,000%. (Complaint, ¶¶ 45, 111-18, 126, 133-34)

Defendants' knowing listing of the invalid patents in the Orange Book constituted additional statements that were material to false claims. Allergan's motion does not discuss this fact in any detail, but it, too, precludes dismissal. 31 U.S.C. § 3729(a)(1)(B).

Allergan argues that its certifications regarding its pricing to the government were not false or fraudulent because "the GSA requires proof that prices are 'fair and reasonable' to ensure that the government is receiving pricing that is commensurate with (or better than) *commercial pricing*," and "not based on an unbounded inquiry into whether the seller is in compliance with every conceivable law that could affect price." (MTD, at 26) This argument is logically flawed. The GSA (and other government payors) base government prices on commercial ones, but that does not mean the government is indifferent about whether the commercial price is itself the product of a massive fraud. Rather, the government *assumes* that the commercial price reflects fair market conditions, and it relies on the commercial price for that reason. Consequently, when, as here, a defendant perpetrates a fraud that preys on the government's core assumption, the fraud taints the government's pricing and therefore the resulting claims for payment. *See, e.g.*, *Campie*, 862 F.3d at 904; 48 C.F.R. § 15.402(a)(2) (providing that in "establishing the reasonableness of the offered prices," a purchasing officer need not obtain "certified cost and pricing data as necessary to establish a fair and reasonable price" only if "the price is based on adequate price competition . . . .");.

The Supreme Court's decision in *Escobar* supports this claim. There, the relator alleged that claims submitted to Medicaid for counseling services were "false and fraudulent" under the FCA when the claims referred to billing codes corresponding to services such as "family therapy" and job titles such as "Social Worker, Clinical." 136 S. Ct. at 1997. The Court held that such claims violated the FCA because the social workers were unlicensed—even though neither the claims nor the billing code descriptions contained an explicit representation the social workers were "licensed" under state law. Focusing on the plain meaning of the FCA and eschewing a "circumscribed" interpretation, the Court held the claims defrauded the government because such qualifications were *implied*. *Id.* at 1997-98 & 2000. As the Court explained, "[a]nyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that the clinic had complied with core Massachusetts Medicaid requirements" relating to training and qualifications. *Id*. at 2000.

The same is true here: Anyone at the government seeing the commercial prices reported by Defendants "would probably—but wrongly—conclude that" Defendants were reporting prices that they had not deliberately manipulated through fraud and anti-competitive conduct. Accordingly, under *Escobar*, the FCA reaches these facts.

Contrary to Allergan's alarmist assertions, recognizing liability in this case would not open the door to FCA cases based on violations of "every conceivable law that could affect price." (MTD, at 26) The fraud in this case was egregious. Its principal purpose was to inflate the price of drugs that the government buys in massive quantities. And its effect on the price the government paid for these drugs was staggering, resulting in a likely markup of 1000%. Whether the FCA creates liability for some other violation, of some other law, with a more attenuated connection to prices, is a question properly left for a future case. In the present case, the question is whether the FCA—which is intended to "reach all types of fraud, without qualification, that might result in financial loss to the Government," *Hendow*, 461 F.3d at 1171—applies to this fraud, which caused the government to pay 10 times the amount it should have paid for prescription drugs.

Allergan next argues that the Complaint does not plead, with particularity, that it actually submitted pricing information to the government in connection with pricing negotiations. (MTD, at 26-27) In this Circuit, however, a Complaint need only plead "particular details of a scheme" with "reliable indicia that lead to a strong inference" that claims have been submitted. *U.S. ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010). The Complaint's allegations, taken as true with all reasonable inferences drawn in favor of Relator, meets that standard because it is implausible that these representations were not made. It is undisputed that Namenda XR and Namzaric *actually are* listed on the FSS (they have to be to qualify for Medicaid reimbursement, which they have received).[8] And it is undisputed that a *requirement* for being listed on the FSS is making representations to the government about the price. To the extent Defendants' arguments cast doubt on *whether* such representations were actually made, the argument would not help Defendants because if they *did not*

[8] The FSS schedule confirming the listing for Namenda XR and Namzaric—and providing specific detail concerning, *inter alia*, the vendor responsible for the listing (Allergan), the date, and the price—can be accessed and downloaded in Excel format at: https://www.va.gov/opal/nac/fss/pharmPrices.asp.

make such certifications and still received payment from Medicaid and government direct purchases, then any claims related to those payments *necessarily* are false for failure to comply with a basic prerequisite for payment. *See, e.g.*, *Campie*, 862 F.3d at 904-05.

Allergan additionally contends that the representations it made to the government about pricing did not include "specific representations about the goods or services provided." (MTD, at 27-28) It is important to note that any such requirement found in the cases cited by Allergan would apply only to a theory based on *implied certification*. *See Escobar*, 136 S. Ct. at 2000-01; *Campie*, 862 F.3d at 901. It does not apply to an FCA theory sounding in promissory fraud, which makes all downstream claims false or fraudulent based on an original, upstream fraud. *See, e.g., Campie*, 862 F.3d at 902. *Both* theories apply to this case.[9]

Moreover, the Complaint does allege that Defendants made "specific representations about the goods or services provided." In particular, Defendants made misleading representations concerning the market and best commercial prices for the drugs, which Defendants were required to disclose to the government. (Complaint, ¶¶ 111-18) Just like the billing codes at issue in *Escobar*, which the Supreme Court deemed "specific representations" about treatment (even though the billing codes said nothing about whether the services were performed by social workers who were "licensed" in Massachusetts), the price information Defendants conveyed to the government in this case concerning the "fair and reasonable" pricing for Namenda XR and Namzaric was misleading because it was tainted by fraud.

Allergan says that the Complaint's allegations concerning false statements to the Patent Office are too "disconnected" from the "invoices submitted to the government" to be actionable under the FCA. (MTD, at 26, *citing United States ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A (E.D. Va. Sept. 29, 2004)) Allergan misleadingly tells the Court that until Relator's suits, only *Promega* and one other case, *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 705 (9th Cir. 2017), had alleged an FCA violation based on the foreclosure of generic competitors—and that

[9] To be clear, Defendants' conduct in fraudulently obtaining patents constituted an upstream fraud that tainted all downstream claims incorporating the inflated, monopoly prices. This supports FCA liability based on *promissory fraud*. Additionally and separately, Defendants' conduct in charging inflated prices—particularly at prices Defendants represented to have been "fair and reasonable"—also supports FCA liability based on an *implied certification* that such prices reflected fair market conditions and were not inflated through the wrongful exclusion of competitors.

"[n]either case survived scrutiny under Rule 12. (MTD, at 4) Defendants' statement omits important details. In fact, *Amphastar* did survive Rule 12 scrutiny but was only dismissed later for reasons that have since been superseded by statute.

In *Amphastar*, the relator alleged that the defendants fraudulently obtained a pharmaceutical patent and used it to block generic entry, thereby inflating the price charged for the drug. The district court held that these allegations stated valid claims under the FCA. *See Amphastar Pharms. Inc. v. Aventis Pharma SA*, No. 5:09-cv-0023-MJG, 2013 WL 12139832, at *3 (C.D. Cal. Apr. 19, 2013); *see also* 2012 WL 5512466, at *9–13 (prior decision explaining sufficiency of legal theory).

Subsequently, after determining that relator's claims were disclosed in prior infringement actions (which qualified as public disclosures prior to the 2010 amendments), the court vacated its prior orders on jurisdictional grounds.[10] 2015 WL 4511573, at *1 (July 20, 2015). The Ninth Circuit affirmed dismissal on those grounds, without addressing the sufficiency of the fraud allegations. *Amphastar*, 856 F.3d 696 (9th Cir. 2017). Had *Amphastar* been filed after the 2010 amendments became effective, any disclosures in the patent infringement actions would not have barred the action, because the government was not a party to those proceedings. *See* 31 U.S.C. § 3730(e)(4)(A)(i).

Allergan's reliance on *Promega* is also misplaced. The Ninth Circuit has explicitly rejected *Promega's* reasoning that there was a "disconnect" between the invoices and the misrepresentations.[11] *See Campie*, 862 F.3d at 903. *Promega* was also decided before the 2010 amendments to the FCA, and its dismissal based on the public disclosure bar is no longer good law. Moreover, this unpublished decision is not binding authority, and the court has removed the decision from PACER.

[10] The court noted that its prior decisions had been questioned in a law review article. *Id.* at *1 & n.5. That article was written by a law student and two associates at defense firms, one of whom represented pharmaceutical companies in patent prosecution. Notably, the cited article concedes that the courts' broad interpretation of the FCA over the years has "made claims like Amphastar's feasible." Gregory Michael, *et al.*, *The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution*, 25 Fordham Intell. Prop. Media & Ent. L.J. 747, 784 (2015).

[11] To the extent Defendants argue that the facts pleaded lack a sufficient nexus to a false claim because the causal chain is too attenuated—which is not true—that issue should be resolved by a trier of fact. *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1049-50 (C.D. Cal. 2016); *cf. Campie*, 862 F.3d at 907.

In sum, the Complaint specifically alleges myriad false statements that rendered all of the claims for payment relating to Namenda XR and Namzeric fraudulent, and Allergan's arguments to the contrary in the motion to dismiss should be rejected.

IV. The Complaint Pleads Materiality

Allergan makes a perfunctory argument about materiality, contending that the government's continued payments for Namenda XR even after the patents protecting it were invalidated in February 2018 disproves materiality as a matter of law. (MTD, at 28-29) That is incorrect. As explained above, the materiality standard is met when either a reasonable person would find information relevant to a payment decision, or when the government would do so (even if a reasonable person would not). The government has expressed time and again its desire to pay less for prescription drugs, including by purchasing generic alternatives. And many government health plans require the purchase of generics when they are available.[12] Consequently, there is no doubt that if Defendants had not fraudulently excluded generics from the market, the government would have bought memantine from those companies at lower prices instead of from Defendants.

Moreover, the price of drugs goes to "the essence of the bargain" between drug manufacturers and the government. *See United States* ex rel. *Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834 (6th Cir. 2018), *cert. denied* 139 S. Ct. 1323 (2019) (noting that this is a factor relevant to materiality). Price is a quintessential material contract term. J. D. Calamari & J.M. Perillo, *The Law of Contracts*, § 2-13, at 43-44 & n. 17 (2d ed. 1977); *see Unihan Corp. v. Max Group Corp.*, 2011 WL 6814044, at *7 (C.D. Cal. 2011) (price of a product is a material contractual term). Courts have held that terms affecting the size of government payments are material under the FCA. *See U.S.* ex rel. *Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018) (misstatement of information that directly influences the amount the government pays is material); *United States v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 102 (D.D.C. 2017) (defendant's claimed

[12] *See, e.g.*, Centers for Medicare & Medicaid Services, Drug Plan Coverage Rules, https://www.medicare.gov/drug-coverage-part-d/what-drug-plans-cover/drug-plan-coverage-rules; Dep't of Health & Human Servs. Office of Inspector General, *Generic Drug Utilization in State Medicaid Programs* (July 2006), at iv, *available at* https://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf (noting that the Centers for Medicare and Medicaid Services "strongly encourages the dispensing of generic drugs.")

costs "were significantly higher than reasonable, so those claims satisfy *Escobar's* materiality standard").

Against this backdrop, the fact that the government has also continued to pay for Namenda XR does not compel dismissal as a matter of law. First, continued payments only speak to the materiality of a legal requirement if the government had actual knowledge of the alleged fraud when it paid for them. The Complaint does not allege that the government ever had such actual knowledge. *See Prather*, 892 F.3d at 834. Indeed, six of the Went Patents have been invalidated for *indefiniteness*, which requires no proof of fraud. Second, even though the government pays for Namenda XR, it also pays for the generic alternatives to Namenda XR. This means that prices, overall, have gone down. Third, ceasing payments for Namenda XR altogether would serve little purpose, and might complicate care for patients who have been using the drug for long periods of time. *See Campie*, 862 F.3d at 906 (fraud was material at the pleading stage even if the government continued to pay because there are many reasons why the government might continue to pay for a drug that have nothing to do with FCA liability or whether the government found the violation to be material).

Because it is at least plausible that Defendants' fraud—which the Complaint alleges had a massive effect on the price the government paid for these drugs—was material to the government's payment decisions, Allergan's materiality arguments should be rejected.

V. Allergan's Public Disclosure Argument Lacks Merit

Allergan's principal argument for dismissal has nothing to do with its own conduct; instead, Allergan argues that even if it committed fraud, Relator's suit must be dismissed because the allegations or transactions alleged in the Complaint were publicly disclosed. The FCA's public disclosure provision provides for the dismissal of an action:

> if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,

> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). A relator is an "original source" if he has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and "has voluntarily provided the information to the Government before filing an action under this section." *Id.* § 3730(e)(4)(B).

In 2010, Congress "overhauled" and "radically changed" the statute to "lower the bar for relators." *United States* ex rel. *Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298–99 (3d Cir. 2016). Prior to those amendments, the public disclosure bar was broader in two important ways. First, it applied to disclosures in every criminal, civil, or administrative hearing or proceeding—not only in federal hearings or proceedings in which the government was a party. Thus, a disclosure in a private lawsuit or an *ex parte* administrative proceeding could have triggered the bar then, but it cannot do so now. Congress narrowed the bar to cases in which the federal government is actually participating, so that it would apply only to litigation that the government was reasonably likely to know about. Second, the definition of an "original source" was narrower. Previously, it required the relator to have "direct" knowledge, meaning firsthand knowledge, of the fraud. Congress removed that requirement to facilitate lawsuits by knowledgeable outsiders.

A. Relator's Allegations of Fraud Have Never Been Publicly Disclosed

Allergan does not identify a single public disclosure of Relator's "allegations" in this case, *i.e.*, that Defendants obtained the Went Patents and the '009 Patent by fraud, and then used those invalid patents unlawfully to exclude competition and charge the government inflated prices.

Instead, Allergan identifies lawsuits about a different drug, Namenda IR, to which the federal government was not a party. Allergan concedes that these lawsuits "did not expressly allege fraud on the USPTO," but argues that they generally alleged "conduct by the Allergan Defendants related to alleged abuse of patents for the Namenda® line of products." (MTD, at 14) That is not enough. Allegations of non-fraudulent misconduct[13] about a different drug are not "substantially the same" as

[13] Allergan's alleged misconduct with respect to Namenda IR involved "hard switch" or "product hopping"; and to unlawful pay-for-delay agreements with competitors—not fraud on the Patent Office.

the fraud alleged in the Complaint. As the Ninth Circuit recently held, "[a]llowing a public document describing 'problems'—or even some generalized fraud in a massive project or across a swath of an industry—to bar all FCA suits identifying specific instances of fraud in that project or industry would deprive the Government of information that could lead to recovery of misspent Government funds and prevention of further fraud." *U.S. ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 577 (9th Cir. 2016). In *Mateski*, "the prior public reports provided 'enough information to . . . pursue an investigation' into some fraud," and indeed "the Government did in fact undertake some investigation," but the Ninth Circuit held that the disclosed fraud was not substantially similar to the relator's claim because "the prior reports could not have alerted the Government to the specific areas of fraud alleged by" the relator. *Id*. at 579. This case is *a fortiori* because the disclosure Allergan identifies would not have provided any reason to investigate the patents related to Namenda XR or Namzaric, and there is no allegation in the Complaint that the government in fact investigated those patents.

Ultimately, Allergan's contention boils down to an absurd suggestion that because Allergan committed crimes in the past to protect its drug monopolies, it can evade liability for any future, unrelated fraud because the government should already know the company is a serial fraudster willing to do anything, no matter how illegal or dishonest, to continue overcharging the government billions of dollars. That is obviously not what Congress had in mind when it amended the FCA.

Allergan also argues that a generic drug manufacturer initiated a proceeding before the Patent Trial and Appeal Board challenging the validity of one of the Went Patents "on anticipation and obviousness grounds." (MTD, at 14) This was not a proceeding to which the government was a party, and Allergan does not even suggest that the challenger alleged fraud on the Patent Office—indeed, it could not have, because the Patent Trial and Appeal Board has no jurisdiction to hear claims based on fraud. *See* 35 U.S.C. § 311(b). The allegations in that proceeding were therefore also not "substantially the same" as the allegations in the Complaint.

B. The Relevant Transactions Were Not Disclosed in an Enumerated Forum

Without any credible argument that Relator's allegations were publicly disclosed, Allergan is left to argue that the "transactions" in the Complaint were disclosed. For the disclosure of transactions to

trigger dismissal, the disclosed transactions must be in a forum enumerated in the statute, *i.e.*, a hearing in which the government is a party, a federal report, or the news media. 31 U.S.C. § 3730(e)(4)(A).

Allergan's key argument is that if the government had reviewed the materials submitted during patent prosecutions, it could have spotted the fraud alleged in the Complaint. Thus, Allergan points to the allegations in the Complaint that Dr. Went submitted a declaration misrepresenting the results of the ME110 Study on November 5, 2010; and then on May 7, 2012, submitted a declaration in connection with a different patent application that included a table accurately reporting the results of the ME110 Study. (Complaint, ¶¶ 62-68) Allergan argues that these two declarations were both accessible in the patent prosecution dockets, which the Patent Office makes available through a website called "Public Patent Application Information Retrieval," or "PAIR." Like the PACER system for courts, PAIR reproduces the vast majority of documents submitted in a patent prosecution. Indeed, as with PACER, documents appear on PAIR in real time as they are filed electronically.[14] The site hosts *millions* of dockets. Allergan argues that the government could have reviewed these dockets, found Dr. Went's declarations, and inferred that Dr. Went defrauded the Patent Office in 2010. (MTD, at 11; *see* Complaint, ¶¶ 63-90) Allergan's argument is unpersuasive because patent prosecutions are not a forum enumerated in the public disclosure bar; indeed, they are carved out of it.

Tellingly, Allergan assiduously avoids any consideration of whether a patent prosecution constitutes a "hearing in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i).[15] This is because patent prosecution is an *ex parte* administrative proceeding in which the government is not a party. Thus, these proceedings fall squarely within the category of hearings that Congress sought to carve out of the public disclosure bar in 2010. Allergan attempts to end-run Congress's amendment by arguing that even though facts disclosed in the proceedings themselves could not qualify as public

[14] *See* https://www.uspto.gov/patents-application-process/checking-application-status/pair-faqs ("Is the information I am viewing in PAIR current? Yes! The information in PAIR is real-time status information.")

[15] For purposes of § 3730(e)(4)(A)(i), a "hearing" is synonymous with "proceeding." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000).

disclosures, the documents reproduced on the docket are "Federal reports" or "news media." This argument is unpersuasive.

First and foremost, Allergan's position cannot be reconciled with the statutory text. In statutory interpretation, the "specific governs the general," *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (quotation marks omitted), and courts are "obliged to give effect, if possible, to every word Congress used," *Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617, 632 (2018) (quotation marks omitted). In 2010, Congress specifically added the phrase "in which the Government or its agent is a party" to the "hearings" subsection of the public disclosure provision, making it clear that it wished to "exclude from the public disclosure bar information disclosed at hearings in cases in which the Government is *not* a party." *Integra*, 2019 WL 3282619, at *11. Allergan's argument would nullify that new limitation for each and every proceeding with a public docket—a tremendous share of private hearings including not only patent prosecutions, but also private federal litigation (for which PACER automatically posts electronically filed documents to the web). This would "swallow limitations that Congress specifically placed on the scope of the public disclosure bar," and "run contrary to the purposes underlying the public disclosure bar, and indeed the FCA itself." *Integra*, 2019 WL 3282619, at *11-12.

Second, Allergan's approach is inconsistent with controlling precedent. Critically, Allergan has not cited a single case—controlling or otherwise—holding that documents available only on PAIR trigger the public disclosure bar under the current version of the statute. It argues that *Amphastar* and *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1241 (9th Cir. 2000), support its position (MTD, at 12-13), but both of those cases applied the pre-2010 version of the FCA—which matters because the disclosure in *Amphastar* occurred in a prior patent infringement action, and the disclosure in *A-1 Ambulance* occurred in local government administrative hearings, neither of which would trigger dismissal under the current statute.

Allergan's approach contradicts the Supreme Court's holding in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011). In *Schindler*, the Court held that "to determine the meaning of one word in the public disclosure bar, we must consider the provision's 'entire text,' read

as an 'integrated whole.'" *Id*. at 408 (citation omitted). The Court stressed that "*all* of the sources [of public disclosure] listed in § 3730(e)(4)(A) provide interpretive guidance." *Id*. at 409 (quotation marks and citation omitted). Under the new statute, Congress's modifications to the "hearings" subsection makes it impossible to read the "reports" and "media" subsections as broadly as Allergan suggests.

Allergan's contention also contradicts *Schindler*'s emphasis on the "ordinary meaning" of the language of the public disclosure bar. In *Schindler*, the Court concluded that a written response to a FOIA request, prepared by federal employees who were required to "notify the person making such request of [the agency's] determination and the reasons therefor," fell within the ordinary definition of a "report." 563 U.S. at 410. But nobody would say that an affidavit, prepared by a private inventor and submitted to the Patent Office in connection with a patent application, constitutes a "Federal report" or "news media." The Patent Office's reproduction of the affidavit does not change this fact because an online docket sheet, by itself, does not fall within the ordinary meaning of a "Federal report" or "news media," either. As noted above, the PAIR system is nothing like a written FOIA response. It posts docket entries online automatically; it does not require federal employees to publish the information—let alone make or communicate a "determination" about what responsive information to include. This result is confirmed by *Integra*, 2019 WL 3282619, at **11-14, which determined that a report that representatives from CMS gathered, compiled, and prepared in response to Relator's request constituted a "federal report" under § 3730(e)(4)(A)(ii).[16]

Third, as Allergan acknowledges, the cases it cites have held that databases available on government websites should qualify as "reports" when they are "readily available" and "easily navigable." (MTD, at 16) (*quoting United States ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, 739 F. Supp. 2d 396, 405, 407 (S.D.N.Y. 2010))[17]; *see also U.S. ex rel. Calilung v. Ormat Indus., Ltd.*, 2015

[16] Allergan's out-of-circuit cases holding that the government's publication of raw third-party information constitutes a "report" are unpersuasive. These cases rely on *Schindler*—but they overread the case, because *Schindler* itself did not involve the mere republication of raw data; the case involved packaging records with a document that clearly fell within the ordinary definition of a report.

[17] *Rosner* is also distinguishable because, unlike the database in *Rosner*, PAIR contains only "raw, unanalyzed data," *i.e.*, the original and unmodified filings submitted in connection with administrative proceedings before the Patent Office. As *Rosner* recognized, for a database to be considered a government report, it must contain more than "raw, unanalyzed data"—it must reflect some "synthesis or organization by the government." *Id.* at 407.

WL 1321029, at *16 (D. Nev. Mar. 24, 2015) (holding that SEC filings are "reports" because they are reproduced on "easily navigable websites"); *Liotine v. CDW Gov't, Inc*., 2009 WL 3156704, at *6 & n. 5 (S.D. Ill. Sept. 29, 2009) (website was not a public disclosure because it required users to take several steps to locate information). The Patent Office's PAIR database is not "easily navigable." It contains the entire histories for millions of patent applications, is difficult to search (and cannot be searched using external search engines), and it utilizes opaque docket sheets providing almost no descriptive information about the contents of particular files.[18] At the very least, legitimate questions about how easy it is to search PAIR preclude ruling for Allergan at the pleading stage.

Fourth, treating the PAIR database as a "Federal report" is contrary to the policies behind the public disclosure provision. The reason that information contained in "Federal reports" is considered publicly disclosed is because the government is likely to know it, and therefore be able to pursue a fraud claim based on it without a relator's assistance. But when, as here, the asserted "report" constitutes a mountain of raw information submitted by third parties, entered into an electronic database as a matter of course and without any effort at synthesis, the assumption of government knowledge breaks down. In this circumstance, it would make no sense to impute knowledge of all of the statements in PAIR to the government. Indeed, the rules governing patent prosecutions impose an affirmative, statutory duty on patent applicants to provide all material information concerning patentability to the Patent Office, particularly prior art that may render a claimed invention obvious. 37 C.F.R. § 1.56. Prior art citations by their very nature are public (and thus are invariably found somewhere on the Internet); and they specifically include all prior patents or patent applications (that

[18] To illustrate: From the home screen, a user can search for a specific patent application by number. To view the original Went Patent application, for example, the user could input the patent or the application number. Once the user finds the desired application, he or she can view the "image file wrapper," which is a complete docket sheet for the application. The entries in that wrapper describe each document only at a high level of generality. For example, Dr. Went's 2010 declaration is labeled with its date and the words "Affidavit-submitted prior to Mar 15, 2013." The docket does not indicate that the affidavit is by Dr. Went, nor reveal its contents. The file can be opened as a PDF, but it is not searchable. This means that unless a researcher already knew where to look, finding Dr. Went's 2010 statement about the ME-110 Study would have been like searching for a needle in a haystack. Finding two conflicting representations about the ME-110 Study in affidavits filed eighteen months apart in connection with two different applications would have been like trying to find two needles in two different haystacks, each surrounded by a field of similar-looking haystacks. In other words, this is not the sort of database that a researcher can simply query for a specific piece of data—and that makes it distinguishable from the cases Allergan cites holding that online databases constitute "reports."

consequently are listed in PAIR). If Allergan's argument is accepted, there could *never* be a *qui tam* action based on a defendant's knowing omission of prior art materials to the Patent Office—even though the disclosure of prior art is one of the most important and fundamental obligations of a patent applicant under the statutory duty of "candor and good faith."

Finally, Allergan's "news media" argument has been rejected by a recent, well-reasoned decision in this Circuit. *See Integra*, 2019 WL 3282619, at *11. The *Integra* court noted that cases treating broad swaths of the Internet as "news media" have ignored the Supreme Court's guidance in *Schindler* to construe terms in the public disclosure bar consistently with their ordinary meaning. No one would call PAIR "news media" in ordinary parlance: The term "generally carries with it a connotation of editorial independence, or at least some separation, between the original source of information and the medium that conveys it." *Id.* at *14. "News media" relates to "communication that are used to convey a particular type of information: information about recent events or that would otherwise commonly be found in a newspaper, news broadcast, or other news source. It follows, then, that the term cannot refer to the internet in general, a channel that is designed to be able to convey essentially anything." *Id.* The same considerations dictate the same result for third-party providers like Westlaw or LexisNexis that repackage government data.

At bottom, Allergan has pointed to literally no case holding that patent prosecution histories constitute either "Federal reports" or "news media." To accept Allergan's interpretation, the Court will have to make new law expanding the scope of these terms. For the reasons given above, it should refuse to do so.

If statements in patent prosecution histories are not qualifying public disclosures, then Allergan's public disclosure argument collapses. Allergan identifies no place other than the patent prosecution files that contain sufficient information to allow anyone to infer that Defendants obtained their patents by fraud.

C. In the Alternative, Relator Is an Original Source.

Even if there has been a public disclosure in an enumerated forum of all the material elements constituting fraud—which did not occur—Relator may still pursue his claims if he is an "original

source" possessing "knowledge that is independent of and materially adds to" the publicly disclosed allegations or transactions. *See* 31 U.S.C. § 3730(e)(4)(B). The question of whether a Relator's knowledge "materially adds to" publicly disclosed allegations or transactions is a fact issue, and it cannot appropriately be resolved on a Rule 12 motion.

Allergan argues that a Relator cannot qualify as an "original source" by applying specialized or technical knowledge to purportedly public information. It is true that Allergan's position is the prevailing view in caselaw interpreting the pre-2010 version of the FCA. But the Ninth Circuit has not yet held that this interpretation applies to the current statute. Indeed, it would be inconsistent with the statutory text to so conclude. Congress intentionally removed the requirement that a Relator have "direct" or first-hand knowledge of the purported fraud. Thus, nothing in the text of the current statute limits a relator's qualifying knowledge to case-specific facts. Instead, any knowledge that is not in an enumerated public disclosure suffices. *Cf. Moore*, 812 F.3d at 305 ("[A] relator's knowledge must be independent of, and materially add to, not all information readily available in the public domain, but, rather, only information revealed through a public disclosure source in § 3730(e)(4)(A)."). In this case, Relator's knowledge about the intricacies of drug patents fits within the statutory text because such knowledge is not part of the public disclosures Allergan identified.

Under the new statute, the key question is whether the Relator's knowledge "materially adds to" the publicly disclosed allegations or transactions. The ordinary meaning of this phrase means that "a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *Moore,* 812 F.3d at 306. When, as here, the Relator undertakes a painstaking inquiry that is impossible without highly specialized expertise, his knowledge "materially adds to" the publicly available information by transforming disparate facts from completely unrelated sources into a coherent narrative of fraud on the government, when no one in the government had even suspected it, much less "alerted . . . to the specific areas of fraud alleged by" the relator—thus improving its quality. *Cf. Mateski,* 816 F.3d 565, 579. For example, a Relator's expertise, gleaned from years as a practicing patent attorney, may enable him to recognize when misleading statements by patent applicants are likely to be intentional (and therefore fraudulent), versus merely negligent. *Cf.*

United States ex rel. Winkelman v. CVS Caremark Corp., 827 F.3d 201, 213 (1st Cir. 2016) ("[F]urnishing information that a particular defendant is acting 'knowingly' (as opposed to negligently) sometimes may suffice as a material addition to information already publicly disclosed."). Or his facility with scientific literature may allow him to determine which of two contradictory declarations describing a scientific or clinical study is false. In either case, the Relator's understanding would "materially add to" the publicly disclosed information in a way that helps the government, and it would be consistent with the purposes of the FCA (including the narrowed public disclosure bar) to hear his claim on the merits.

VI. Allergan's State Law Arguments Fail

Because Relator has adequately pleaded federal FCA claims, the state claims should be upheld. The Complaint also plausibly alleges that claims for Namenda XR and Namzaric were made in every Plaintiff State.[19] The Complaint alleges that in 2016, Medicaid reimbursed 107,899 claims for Namenda XR and 2,105 claims for Namzaric. (Complaint, ¶136) CMS data confirm that substantial false claims to Medicaid were made in every Plaintiff State except for Delaware and Rhode Island.[20]

The Texas Attorney General has requested Relator to inform the Court that the Texas causes of action do not require the presentment of a false claim, and most do not require proof of materiality. Tex. Hum. Res. Code §§ 36.002(1)-(13). Therefore, Defendant's arguments on these issues do not apply uniformly to Texas.

CONCLUSION

For the foregoing reasons, the Motion to Dismiss should be denied in its entirety. In the alternative, the Court should permit Relator to amend his pleadings should there be any deficiency.

[19] Allergan argues that the claim relating to New Mexico should be dismissed because the Complaint contains no allegation that there has been a "substantial evidence" determination. That is not a proper basis for dismissal under Rule 12 unless the complaint has been amended after the action has been unsealed and the states have had an opportunity to make an intervention decision. *Compare U.S.* ex rel. *King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520 (S.D. Tex. 2011*), order vacated in part on reconsideration*, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012), *with Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015).

[20] CMS Medicaid utilization data for Namenda XR and Namzaric, sortable by state in which the claims were submitted, are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.html.

Respectfully submitted,

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HERRERA PURDY LLP

By: */s/ Nicomedes Sy Herrera*
Nicomedes Sy Herrera

Nicomedes Sy Herrera (State Bar No. 275332)
Laura E. Seidl (State Bar No. 269891)
HERRERA PURDY LLP
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
Email: NHerrera@HerreraPurdy.com
LSeidl@HerreraPurdy.com

Andrew Purdy (State Bar No. 261912)
HERRERA PURDY LLP
4590 MacArthur Boulevard, Suite 500
Newport Beach, California 92660
Email: APurdy@HerreraPurdy.com

Tejinder Singh (*Pro Hac Vice*)
GOLDSTEIN & RUSSELL, P.C.
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
Email: TSingh@GoldsteinRussell.com

Attorneys for Plaintiff-Relator Zachary Silbersher